IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' REPLY TO PLAINTIFFS' RESPONSE TO MOTION TO EXCLUDE CERTAIN OPINIONS OF JERRY G. BLAIVAS, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants") submit this reply brief in support of their motion to exclude certain opinions of Jerry G. Blaivas, M.D.

I. The Court should preclude Dr. Blaivas from testifying that TVT Devices are not safe in the treatment of SUI.

A. Dr. Blaivas has conceded that whether the complications are the result of surgeon error or characteristics of the mesh is unknown and that he employs different standards.

Citing *Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048, at *15 (S.D. W. Va. May 5, 2015), Defendants have argued that the Court should preclude Dr. Blaivas from testifying that certain sling devices are not safe in the treatment of SUI because he admitted that he utilizes a different standard for medical literature than he employs when providing opinions in litigation. *See also Flores-Banda v. Boston Scientific Corp.*, 2016 U.S. Dist. LEXIS 60984, at *34-35 (S.D. W. Va. May 9, 2016). Plaintiffs ask the Court to reject this argument because this Court found Dr. Blaivas competent to testify about these issues in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 718 (S.D.W. Va. 2014), and *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 521 (S.D. W. Va. 2014). The Court, however, did not consider this argument in those cases.

According to Dr. Blaivas, "I phrase my words differently in the peer-reviewed literature than I do in the legal literature because it's two different sets of rules" and that "words mean different things in the medical literature than they do in legal literature." Ex. J to Def's Motion at 391, 397. Plaintiffs now claim that Dr. Blaivas has subsequently modified his testimony in the Boston Scientific cases so as to testify that he really did not mean what he said and that he actually employs the same standard after all for both his medical practice and his expert witness practice. Such an attempt to modify his testimony, however, should be treated the same way as a "sham affidavit." *White v. Dow Chemical, Co.*, 2007 WL 6948824, at *4 (S.D. W.Va. Nov. 29, 2007),

Citing solely pages 398-399 of Dr. Blaivas's September 24, 2015 deposition, Plaintiffs also claim that "Dr. Blaivas testified at lengthy about . . . the fact that the methodology that he used in his expert reports is the same as the methodology utilized when preparing his peer reviewed publications." Doc. 2176, pp. 6-7 (citing Ex. H to Def's Motion). Yet, the cited testimony lends no support whatsoever to Plaintiffs' assertion.

Plainly, the standards employed by Dr. Blaivas in the medical literature that he wrote before his *Wilkerson* testimony did not suddenly change after his *Wilkerson* testimony. Because he has employed different standards, the Court should follow *Wilkerson* and its other rulings and preclude Dr. Blaivas from testifying that TVT Devices are unsafe for the treatment of SUI.

B. Dr. Blaivas's opinions about TVT Devices are premised on an unreliable assessment of complications and complication rates.

1. "Unreliable Minimum 12.5% Complication Rate Opinions"

In their response, Plaintiffs still offer no explanation as to how Dr. Blaivas has calculated that TVT has a minimum 12.5% complication rate.

2. Selective Choosing

Plaintiffs' response does not provide a meaningful explanation for Dr. Blaivas's failure to account for contrary studies.

3. Flawed Assessment of Pain, Dyspareunia & Sexual Dysfunction Data

Plaintiffs make no attempt to deny that Dr. Blaivas's opinions in this case about pain and dyspareunia are inconsistent with his own 2015 review article, which calculated that only 1.8% of retropubic mesh (like TVT) patients have pain more than six weeks postoperatively. Ex. H to Def's Motion, Sept. 2015 Dep., Ex. 4, p. 5. Plaintiffs claim that Defendants ignored Dr. Blaivas's offer to find a study that indicates that patients continued to have pain at six months or later postoperatively. *See* Ex. H to Def's Motion, Sept. 2015 Dep. 259:15-261:1. It has now been many months since Dr. Blaivas's deposition, and no such study has been identified.

4. Flawed Assessment of Erosion/Exposure/Extrusion Data

Plaintiffs have fallen woefully short of showing that Dr. Blaivas's opinions about TVT erosion, exposure, and extrusion are anything beyond an improper *ipse dixit*.

5. Flawed Assessment of Infection Data.

Plaintiffs ignore that the Culligan paper cited by Dr. Blaivas in support of his infection opinions actually contradicts his opinions. Quite simply, Dr. Blaivas's report cites no reliable basis for his opinions, and this is an area beyond his expertise.

II. The Court should preclude Dr. Blaivas from testifying that traditional surgical approaches are a safer alternative to the devices at issue.

A. Traditional surgical approaches are not a device, and therefore, irrelevant.

For the reasons set forth in Defendants' previous briefing, the Court should not allow Dr. Blaivas to compare TVT with autologous slings, because the latter are not medical devices.

B. Dr. Blaivas improperly bases his opinions about the benefits of autologous slings solely on his own unreliable personal experiences.

In their initial brief, Defendants noted that Dr. Blaivas's opinions that TVT Devices present a heightened risk of complications as compared to autologous slings are based solely on his own personal experiences. In response, Plaintiffs assert that Dr. Blaivas's opinions are further supported by the medical literature. Doc. 2176, p. 19. Yet, Dr. Blaivas has acknowledged that the medical literature on autologous slings is "poor." Ex. H to Def's Motion, Blaivas Sept. 2015 Dep. 97:20-98:5. According to Dr. Blaivas: "[M]y opinion for safety is based not only on the medical literature, which I've already said I think when it comes to safety is poor, by my review on what's not in the literature. So I suppose in a sense that's a review of the literature. So, I'm going to say, yes, it is based on the medical literature." *Id.* at 404:18-24.

Such an opinion is hopelessly unreliable. Incredibly, Plaintiffs argue that Dr. Blaivas's personal experiences are supported by the medical literature, but yet, state that the absence of reliable medical studies to support his opinions is "irrelevant." Doc. 2176, p. 20. The only studies that Plaintiffs reference in their responses to support Dr. Blaivas's opinions are "studies by Eric Rover and Roger Dmochowski's group" that Dr. Blaivas mentioned during his deposition. *Id.* at 21. Yet, Dr. Blaivas admitted that he did not reference those studies in his report, and they are not listed as exhibits to Plaintiffs' response. Ex. H to Def's Motion, Blaivas Sept. 2015 Dep. 106:18-23.

Thus, the question becomes whether Dr. Blaivas's personal experiences alone are sufficient to satisfy the rigors of *Daubert* scrutiny. Succinctly, it is unreliable for Dr. Blaivas to base his opinions on a comparison of the experiences of his own autologous sling patients, alone, with the experiences of other physicians' synthetic sling patients.

The fatal fallacy of Plaintiffs' logic is illustrated in the following hypothetical: Suppose Nike and Titleist are engaged in a lawsuit, and an issue involves which company's golf ball travels farther. The proof shows that the industry driving average (averaging both pro and semi-pro golfers) for Titleist golf balls is 250 yards, which is greater than the Nike average. Nike seeks to present as an expert witness Tiger Woods, who testifies as follows: "I have never hit Titleist golf balls. I don't know how far most golfers drive Nike golf balls, but I know that I drive Nike golf balls an average of 300 yards. Because I personally drive Nike golf balls farther than the Titleist industry average, it is my expert opinion that Nike golf balls travel farther than Titleist golf balls." This would be junk science.

III. The Court should preclude Dr. Blaivas from offering design opinions, such as testifying that other synthetic mesh devices offer safer alternatives.

A. Dr. Blaivas is not qualified.

The Court should follow its prior rulings and determine that Dr. Blaivas is not competent to provide design opinions. *Tyree*, 54 F. Supp. 3d at 561; *Wilkerson*, 2015 WL 2087048, at *15; *Flores-Banda*, 2016 U.S. Dist. LEXIS 60984, at *35-36. Further, in their response, Plaintiffs ignore that they objected to deposition questions about Dr. Blaivas's design opinions as being "beyond the scope" and that Dr. Blaivas, himself, testified that "I hadn't ever thought about [sharing design opinions] in public." Ex. H to Def's Motion, Sept. 2015 Dep. 129:4-12. Thus, Plaintiffs may not now seek to "slip in" such opinions.

B. Dr. Blaivas's weight/pore size opinions are unreliable.

Plaintiffs do not dispute that Dr. Blaivas is unwilling to stand behind any other synthetic mesh devices as being safer feasible alternatives to TVT. Nor have Plaintiffs identified any studies demonstrating that lighter weight, larger pore mesh is safer than and as effective as TVT Devices. According to Plaintiffs, Dr. Blaivas's opinions are "supported by the medical

literature," but Plaintiffs do not attach any such literature and fail to acknowledge that this assertion is contradicted by Dr. Blaivas's own acknowledgment of a lack of such literature. Doc. 2176, p. 22; Ex. H to Def's Motion, Blaivas Sept. 2015 Dep. 124:16-125:14, 141:18-142:5.

Notwithstanding Plaintiffs' assertion, Dr. Blaivas's 2015 article does not support his assertion, but instead, contradicts it. According to Plaintiffs, "In addition to his own article, Dr. Blaivas cites to an additional six (6) scientific articles which support his opinions regarding clinical outcomes with lighter-weight mesh." Doc. 2716, p. 23 (citing fn. 88 to Ex. B to Def's Motion, TVT Report). Yet, Footnote 88 merely cites to *two* articles that involve *hernia* mesh. Given that Dr. Blaivas has identified no reliable evidence that these devices would have been equally effective as a treatment for SUI or POP if the mesh were lighter and had larger pores and given that Dr. Blaivas has identified no reliable evidence that the devices would not have had an increased risk of other adverse events if they had those characteristics, his opinions do not pass muster under *Daubert.*

C. Dr. Blaivas's opinions about the cutting of TVT Device mesh are unreliable.

According to Plaintiffs, Dr. Blaivas's criticisms about the cutting of the mesh are well-supported by . . . the scientific literature." Doc. 2176, p. 23. Yet conspicuously absent from Plaintiffs' response and from Dr. Blaivas's report is the citation to one single article in the scientific literature that supports his opinions. Given the lack of any reliable foundation for his opinions and Dr. Blaivas's failure to stand behind either cutting of the mesh as a suitable alternative, the Court should preclude him from opining about this topic. *See Huskey*, 29 F. Supp. 3d at 712-13.

D. Dr. Blaivas's opinions about TVT implantation design are unreliable.

Plaintiffs' response completely ignores that Ethicon, unbeknownst to Dr. Blaivas, marketed a "top to bottom" TVT device. Although Plaintiffs suggest that Dr. Blaivas's report includes "numerous citations" in support of the notion that a "top to bottom" approach leads to fewer complications, neither Plaintiffs' response nor Dr. Blaivas's report references any scientific data that supports this.

E. Dr. Blaivas's opinions about TVT-O and TVT-Abbrevo are unreliable.

Plaintiffs do not dispute that Dr. Blaivas's criticisms of TVT-O in Section II.5 of his TVT-O report and his criticisms of TVT Abbrevo set forth in Section II.32 of that report are not supported by a single study. Ex. C & F to Def's Motion. These opinions are wholly unreliable and should be excluded.

IV. The Court should limit Dr. Blaivas's biomaterials opinions, such as testimony about alleged mesh degradation, shrinkage, and other deformations.

Plaintiffs ignore that Dr. Blaivas has conceded that "the biochemistry and stuff was over my head" and that "I think experts that are more expert at this than me should look into this in more depth." Ex. U to Def's Motion, 1/30/14 Dep. 482:12-13, 484:17-19. As in *Tyree* and *Huskey*, the Court should find that Dr. Blaivas is not competent to render biomaterials opinions. 54 F. Supp. 3d at 562; 29 F. Supp. 3d at 722.

Plaintiffs claim that those rulings are distinguishable because, after those rulings, Dr. Blaivas published his 2015 *Nature* article. Plaintiffs, however, disregard that Dr. Blaivas testified that he deferred to Dr. Vladimir Iakovlev for those portions of the article that pertained to degradation and biomaterials. Ex. H to Def's Motion, Blaivas Sept. 2015 Dep. 50:7-19. Although Dr. Blaivas claimed that he had "vetted" Dr. Iakovlev's opinions with certain other pathologists, he refused to identify those other pathologists and conceded that he still has no

expertise in pathology. *Id.* at 50:19-54:17. Federal courts have consistently precluded experts from testifying on matters in which they blindly rely on another expert's opinions without performing their own independent analysis. *See, e.g., United States v. Corey*, 207 F.3d 84, 100 (1st Cir. 2000).

These topics are suddenly no longer "over [Dr. Blaivas's] head" merely because he co-wrote an article with a pathologist who handled those portions of the article. Further, Plaintiffs do not meaningfully address Defendants' argument that, even if Dr. Blaivas were somehow qualified, his opinions are unreliable.

V. The Court should preclude testimony about inflammatory alleged conditions.

Plainly, Plaintiffs hope to inflame the juries in these cases by eliciting testimony from Dr. Blaivas about death, "mesh cripples," "chronic mesh syndrome" and other prejudicial matters. In a futile attempt to distinguish these cases from the Court's prior rulings, Plaintiffs assert that "unlike in *Huskey* where the key inquiry for the jury was whether a single plaintiff's injuries were caused by Defendants' product, the relevant inquiry here is whether six (6) of Defendants' devices and procedures are reasonably safe and can cause harm to women" and that "Dr. Blaivas' opinions regarding the increasing number of women with disabling injuries is clearly relevant to the safety of Defendants' devices in women . . . ." Doc. 2176, p. 26. Plaintiffs are wrong. Each of these cases will be tried separately on its own merits. Other Plaintiffs' alleged experiences are wholly irrelevant, and admission of such evidence would be highly prejudicial and a waste of time.

VI. The Court should exclude Dr. Blaivas's product warning opinions.

Should the Court find that Dr. Blaivas is competent to provide product warnings opinions despite his concession that he is not an expert at developing warnings and labels, the Court should also find that Defendants' clinician experts with similar experience are also qualified to

provide such opinions. In any event, Plaintiffs do not respond to Defendants' argument that Dr. Blaivas may not criticize the warnings for not providing sufficient specificity. *See* Ex. B to Def's Motion, TVT Report at II.32. Therefore, such testimony should plainly be precluded.

VII. The Court should not allow Dr. Blaivas to testify about testing.

According to Plaintiffs, "[t]his Court has not previously excluded Dr. Blaivas' testing opinions." Doc 2176, p. 27. Yet, in *Huskey*¸ the Court quite clearly ruled:

> I **FIND** that Dr. Blaivas is not qualified to render opinions relating to the product testing. There is no indication in the record that Dr. Blaivas has any experience or knowledge on the appropriate testing amedical device manufacturer should undertake.

29 F. Supp. 3d at 723. Not only is Dr. Blaivas not competent to testify about testing, he can only speculate about what hypothetical testing would have revealed.

VIII. The Court should preclude Dr. Blaivas from offering certain unreliable opinions suggesting bias, "industry manipulation," and collusion.

In their response, Plaintiffs identify no foundation for Dr. Blaivas's suggestion that Defendants have "manipulat[ed] data" and "colluded with" other medical device manufacturers. Ex. G to Def's Motion, Prolift Report at 14, 16; Ex. B to Def's Motion, TVT Report at II.37, 39. Further, Plaintiffs provide no indication of Dr. Blaivas's methodology for formulating these opinions or opinions about alleged bias. Such opinions are wholly unreliable and beyond Dr. Blaivas's expertise as a urologist.

CONCLUSION

For the foregoing reasons and those set forth in Defendants' initial brief, Defendants respectfully request that the Court limit Dr. Blaivas's trial testimony in these cases.

Respectfully Submitted,

/s/ William M. Gage
William M. Gage
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4561
william.gage@butlersnow.com

/s/ David B. Thomas
David B. Thomas (W. Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

COUNSEL FOR DEFENDANTS
ETHICON, INC. AND
JOHNSON & JOHNSON

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, William M. Gage, certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage

William M. Gage
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4561
william.gage@butlersnow.com

31154118 v1